

**Before the  
FEDERAL COMMUNICATIONS COMMISSION  
Washington, D.C. 20554**

In the Matter of	)	
	)	
Investigation of the Spectrum	)	ET Docket No. 06-135
Requirements for Advanced Medical	)	
Technologies	)	
	)	
Amendment of Parts 2 and 95 of the	)	RM-11271
Commission's Rules to Establish the	)	
Medical Device Radio Communications	)	
Service at 401-402 and 405-406 MHz	)	
	)	
DexCom, Inc. Request for Waiver of the	)	ET Docket No. 05-213
Frequency Monitoring Requirements of	)	
the Medical Implant Communications	)	
Service Rules	)	
	)	
Biotronik, Inc. Request for Waiver of the	)	ET Docket No. 03-92
Frequency Monitoring Requirements for	)	
the Medical Implant Communications	)	
Service Rules	)	

**COMMENTS OF BIOTRONIK, INC.**

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Dated: October 31, 2006

## SUMMARY

Biotronik, Inc. (“Biotronik”), a pioneer in the development of RF-enabled medical implant devices, applauds the Commission for beginning to address important issues relating to the spectrum requirements of such devices. While Biotronik does not oppose the addition of two MHz of spectrum to the existing MICS band, it strongly opposes the segregation of certain devices into the newly-added “wing bands.” Segregating the 401-406 MHz band in the manner proposed in the *Notice of Proposed Rulemaking* is unnecessary because devices that use listen-before-transmit (“LBT”) can easily coexist with low-power, low-duty-cycle (“LPLDC”) devices without causing interference. Such segregation would be a departure from Commission policy of encouraging flexible spectrum use, and would in fact prohibit the important benefits and efficiencies that would result from combining LBT and LPLDC operating modes in a single device.

Biotronik welcomes the proposal to permit LPLDC devices that do not use frequency monitoring in the 401-406 MHz band. However, rather than being limited to the wing bands, such devices should be permitted to operate at a single 300 kHz channel centered at 403.65 MHz with a low maximum power of 100 nW EIRP and a low duty cycle. Such LPLDC devices pose a negligible risk of interference to LBT devices operating in the current MICS band. Moreover, the LPLDC access method offers several significant advantages over the LBT approach, including simplified device design, lower costs, longer service life, and

increased reliability. Finally, keeping LPLDC in the existing MICS band will enable less complex and less expensive dual use devices, and will facilitate the use of a “beacon” channel which would lower power consumption and which would be very spectrally efficient.

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**COMMENTS OF BIOTRONIK, INC.**

Biotronik, Inc. ("Biotronik") applauds the Commission for initiating the above-captioned proceeding to address important issues relating to the use of spectrum by medical implant devices. Biotronik does not oppose the addition of two MHz of spectrum to the existing MICS band, but strongly opposes the segregation of certain devices into the new 401-402 MHz and 405-406 MHz wing bands. Instead, Biotronik supports a low-power, low-duty cycle access method for implants using a 300 kHz channel centered at 403.65 MHz, rather than limited to the wing bands as proposed in the Notice of Proposed Rulemaking ("NPRM").

## **I. INTRODUCTION**

Biotronik is a pioneer in the development of RF-enabled medical device implants, namely implantable pacemakers (“IPGs”) and implantable cardioverter defibrillators (“ICDs”), operating worldwide within the 402-405 MHz band for over five years. Biotronik’s cardiac implant devices transmit operational, diagnostic and therapeutic information to healthcare professionals via the public switched telephone network, both wireline and wireless. Biotronik’s remote monitoring technology allows diagnostic and trend data, and other medically valuable information, of cardiac patients to be transmitted from these implants at any time from almost anywhere in the United States. Previously, this type of data could only be collected infrequently during office visits by the implant patient to his or her physician quarterly or annually.

Currently, Biotronik’s cardiac implant devices that operate in the 402-405 MHz band include the Philos DR-T, Philos II DR-T, and Cylos DR-T pacemakers, as well as Belos VR-T, Belos DR-T, Lumos VR-T, Lumos DR-T, Lexos VR-T, Lexos DR-T, Cardiac Airbag-T, and Xelos DR-T ICDs. In addition, the Biotronik Kronos DR-T, which is a Cardiac Resynchronization Therapy ICD, operates in this frequency band. One of the modes of transmission offered by Biotronik’s devices involves periodic scheduled transmissions that do not follow the listen-before-transmit (“LBT”) frequency monitoring protocol, pursuant to a waiver

granted by the Commission in February 2004.<sup>1</sup>

## **II. BIOTRONIK OPPOSES ANY RULE CHANGE THAT WOULD RESTRICT CURRENT USE OF THE MICS/MEDRADIO BAND**

While Biotronik believes there is ample capacity in the current Medical Implant Communication Service (“MICS”) band, it does not oppose the addition of two megahertz of spectrum for use by medical devices as long as use of the entire 401-406 MHz band is not fragmented into sub-bands that are restricted by operating characteristics, and low-power, low-duty cycle (“LPLDC”) access remains in the present MICS band. As explained below, there is no technical or regulatory reason to segregate devices that use LBT from LPLDC devices. Segregating the 401-406 MHz band in the manner contemplated in the *NPRM* would be a departure from Commission policy of encouraging flexible use of spectrum<sup>2</sup> and is unnecessary because LBT and LPLDC devices can easily coexist in the current MICS band without causing harmful interference to each other. In fact, permitting both LBT and LPLDC access methods to coexist will offer important benefits and efficiencies by allowing the combination of LBT and LPLDC operating modes in a single device.

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<sup>1</sup> *Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Order, 19 FCC Rcd 4208 (2004) (“Biotronik Waiver”).

<sup>2</sup> See 47 U.S.C. § 303(y) (giving the Commission authority to allocate spectrum “so as to provide flexibility of use”); Spectrum Policy Task Force Report, ET Docket No. 02-135, at 16-17 (Nov. 2002) (discussing advantages of and recommending FCC policies promoting flexible spectrum use) (“Spectrum Policy Task Force Report”).

**A. Biotronik Does Not Oppose Addition of New Spectrum to the Existing MICS Band but Strongly Opposes the Segregation of Certain Devices into the “Wing” Bands**

Biotronik does not oppose the grant of an additional 2 MHz of spectrum *provided that* such additional spectrum is not used as a justification for requiring that low power “unidirectional” devices be confined exclusively to such “wing” bands. Specifically, LPLDC access devices should be permitted to remain in the current MICS band.<sup>3</sup> As explained below, and as discussed in further detail in the following section, allowing devices that use the LPLDC access method to remain in the current MICS spectrum (402-405 MHz) raises few concerns of harmful interference and would be consistent with Commission policy permitting flexible spectrum use. By permitting flexible but non-interfering spectrum use in the current MICS band instead of limiting the use of different portions of the band to certain technologies or devices, the Commission would let the medical device manufacturers decide which technology or technologies are better suited for their devices and give them the flexibility they need to design a variety of devices that meet important medical and therapeutic needs.

As Biotronik has explained in prior filings, devices that use LPLDC — which the Commission proposes to confine to the 401-402 MHz and 405-406 MHz bands — pose little risk of harmful interference to devices that use LBT

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<sup>3</sup> While Biotronik supports LPLDC devices being permitted to remain in the existing MICS band, Biotronik sees no reason why LPLDC devices should not be permitted in the entire 401-406 MHz band given the negligible risk of interference presented by such devices.

frequency monitoring technology.<sup>4</sup> The LPLDC access method discussed in the *NPRM* and in the following section involves limited-duration, low-power transmissions that will not risk harmful interference to LBT devices, a fact which the Commission recognized when it granted waivers for LPLDC devices manufactured by Biotronik and low duty cycle devices manufactured by DexCom.<sup>5</sup>

As detailed in a recent *ex parte* filing, Biotronik estimates that the probability of interference between systems using LPLDC and systems using LBT is negligible, on the order of  $9 \times 10^{-5}$ .<sup>6</sup> Not only is this probability of interference negligible, it is also less than the inherent probability of LBT device-to-LBT device interference. Even though LBT is designed to monitor available frequencies before transmission so as to reduce interference, it is well understood that using LBT does not eliminate interference.<sup>7</sup> LBT-LBT interference can result from several different scenarios, such as: (1) an LBT device scanning during transmission gaps of potentially-interfering devices; (2) multiple LBT devices

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<sup>4</sup> Note that interference between two or more LPLDC systems has been shown to be virtually nonexistent, as demonstrated by Biotronik experience and presented in earlier FCC filings. See *Request for Waiver of Biotronik, Inc.*, ET Docket No. 03-92, at 5-6 (Mar. 27, 2003); *Ex Parte* Filing by Biotronik, Inc., ET Docket No. 06-135, RM-11271 (Sep. 25, 2006).

<sup>5</sup> Biotronik Waiver at 4212; *DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, Order*, ET Docket No. 05-213, FCC 06-1, para. 16 (rel. Jan. 18, 2006) (“DexCom Waiver”).

<sup>6</sup> *Ex Parte* Filing by Biotronik, Inc., ET Docket No. 06-135, RM-11271 (Sep. 25, 2006).

<sup>7</sup> See, e.g., *Unlicensed Operation in the TV Broadcast Bands, Additional Spectrum for Unlicensed Devices Below 900 MHz and in the 3 GHz Band*, First Report and Order and Further Notice of Proposed Rulemaking, ET Docket Nos. 04-186 & 02-380, FCC 06-156, para. 39 (rel. Oct. 18, 2006) (describing the “hidden node” problem that affects spectrum sensing technologies such as LBT).

choosing the same “least interfered channel” in the current MICS band in dense environments; (3) asymmetric transmission power, where the interference from a higher power programmer is not detected because scanning does not detect a lower power implant; and (4) the “hidden node” problem, where scanning does not detect a distant transmitter, particularly one “hidden” by a wall or other spatial element, but whose companion transmitter is close enough to interfere.

Biotronik estimates that the probability of LBT-LBT interference caused by the hidden node scenario alone in a typical physician’s office environment is of the order of 0.0122 – still very low but *significantly* higher than the estimated probability of LPLDC-to-LBT interference.<sup>8</sup> Thus, the supposed threat of harmful interference to LBT devices is in fact virtually nonexistent and therefore an insufficient basis for segregating LPLDC devices into the 401-402 MHz and 405-406 MHz wing bands.

Moreover, the effects of whatever minuscule risk of interference presented by LPLDC devices operating in the 402-405 MHz band can be eliminated by well-established mitigation techniques that already are available in medical implant devices.<sup>9</sup> Such mitigation techniques include retransmission of “missed” packets, cyclic redundancy checks (CRC) with error correction, adaptive frequency agility, and fail-safe device operation designed to maintain device

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<sup>8</sup> Biotronik estimated the probability of LBT-LBT interference using the statistical interference analysis techniques that it used in its LPLDC-LBT interference analysis, *see infra* note 19, and using assumptions consistent with such analysis.

<sup>9</sup> In this context, interference means that a “packet” of information sent in the RF transmission is lost.

therapy in the rare and fleeting event of loss of communication due to interference. These mitigation techniques are in fact required to maintain safe device operation in light of the status of MICS as a secondary user of the 402-405 MHz band.<sup>10</sup>

The fragmentation of the 401-406 MHz band by preserving the 402-405 MHz band for more “critical devices” to “protect their function” is contrary to the intent of the original decision to allocate MICS spectrum, as well as the Commission’s conclusions in the Biotronik and DexCom waiver decisions.<sup>11</sup> This approach also is contrary to the worldwide allocation of the MICS band as secondary to METAIDS transmitters. In other words, MICS devices must accept interference from METAIDS devices, a fact that is inconsistent with attempts to preserve the 402-405 MHz band for so-called “critical devices.” The original FCC Order establishing the MICS band rules did not limit use of the band to “critical devices.” As the Commission acknowledges in the *NPRM*, it is neither the role

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<sup>10</sup> See 47 C.F.R. § 95.1211(c) (requiring MICS stations to accept interference from Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services). In Europe, all members of the relevant ETSI working group accepted the following statement: “It follows that systems safety cannot rely on the transmission reliability of a single telemetry session. ULP-AMI system designers will need to incorporate techniques to address possible interference and dropped sessions.” See ETSI ERM TG30, Minutes of the TG30#7 Meeting, Mar. 4, 2005. (ULP-AMI refers to Ultra Low Power Active Medical Implants.)

<sup>11</sup> Note that in consenting to the operation of Biotronik’s LPLDC devices operating within the existing MICS band pursuant to the waiver, NTIA specifically conditioned its consent on the waiver applying to non-critical communications only – a fact that is inconsistent with the proposal to exclude “non-critical” devices from the 402-405 MHz MICS band. See Letter from Frederick R. Wentland, Acting Associate Administrator, Office of Spectrum Management, NTIA, to Edmond J. Thomas, OET, FCC, May 22, 2003, at 2.

nor the area of expertise of the Commission to draw distinctions between “critical devices” and others.<sup>12</sup> The proposal to segregate the band by preserving the 402-405 MHz band for “critical devices” and limiting “non-critical” devices to the wing bands conflicts with this assessment.<sup>13</sup>

**B. Biotronik Opposes More Stringent Emission Limits for Any Portion of the 401-406 MHz MedRadio Band**

The Commission should not adopt more stringent attenuation limits in the 401-402 MHz and 405-406 MHz wing bands, whether this is accomplished with narrower guard bands or lower absolute limits.<sup>14</sup> Stricter spurious emissions will require an unnecessary increase in the complexity of the implant and will require increased cost and power consumption. Moreover, more stringent limits are unnecessary given the low probability of interference from intentional co-channel emissions (as discussed in further detail above), let alone from spurious emissions several orders of magnitude lower. The Commission should maintain the same emissions limits throughout the entire MedRadio band, as this will provide greater flexibility to device manufacturers and simplify product design.

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<sup>12</sup> NPRM at para. 24.

<sup>13</sup> It is also important to recognize that while implant devices may be inherently “life-critical” – *i.e.*, they provide life-critical therapy – it does not necessarily follow that the implant devices’ transmissions are life-critical. The typically unstable RF environment precludes manufacturers from relying on RF transmissions for life-critical operations.

<sup>14</sup> See NPRM, para. 21 & n.48.

**III. BIOTRONIK SUPPORTS THE PROPOSAL TO PERMIT LPLDC DEVICES IN THE MEDRADIO BAND, BUT SUCH DEVICES SHOULD BE PERMITTED IN THE EXISTING MICS BAND RATHER THAN BEING LIMITED TO THE WING BANDS**

Biotronik welcomes the proposal to permit in the 401-406 MHz MedRadio band LPLDC devices that do not use frequency monitoring. However, as discussed above, Biotronik strongly opposes the proposal to segregate such devices by restricting them to the wing bands. Instead, Biotronik supports permitting LPLDC implant devices to use a 300 kHz channel centered at 403.65 MHz with a low maximum power of 100 nW EIRP and a low duty cycle.<sup>15</sup> A single channel is sufficient for LPLDC devices given the low power and low duty cycle utilized by such devices.

At the same time, limiting LPLDC devices to a single channel would accommodate the concerns of interference to LBT devices — however unfounded Biotronik believes those concerns are — because the remaining nine channels (or fifteen if the wing bands are taken into consideration) will have essentially zero probability of interference from LPLDC. By giving device manufacturers more flexibility in the technologies they could employ, the Commission would encourage the development and use of a wider variety of devices that would serve a wider variety of therapeutic and diagnostic needs.

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<sup>15</sup> Biotronik has proposed a duty cycle of 0.1% per hour in its Petition for Rulemaking, but is open to considering other values in that range, such as 0.01%, that preserve the desired functionality of LPLDC systems.

**A. The Low-Power Low-Duty-Cycle Access Method Provides Several Significant Advantages over the Listen-Before-Transmit Approach**

LPLDC offers several advantages over LBT, including both technical advantages and those relating to international harmonization. The LPLDC access method would help achieve the goal of simplifying the transmission of information for applications that are unlikely to experience or cause interference. LPLDC is a simplified access method that reduces the timing and synchronization requirements between implants and external devices. LPLDC could also be used to regulate communications upon “medical implant events,” while reducing spectrum usage and reducing transmission latencies for such communications. LPLDC also enables automatic operations, thereby reducing patient compliance requirements and making the devices easier to use. By enabling less complex radio design and lower power consumption, LPLDC permits simplified device design, lower costs, and lower power consumption, translating to longer service life and increased reliability.

Furthermore, the LPLDC proposal advanced by Biotronik, including the frequency allocation at 403.65 MHz and the 300 kHz channel bandwidth, is consistent with existing standards in Europe, Canada, and Australia that allow LPLDC access within the existing MICS band.<sup>16</sup> Such a consistent operating

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<sup>16</sup> In Europe, LPLDC access is consistent with the ETSI published standard ETSI EN 301 839-2 v1.1.1 (2002-06), Table A.1 (without a duty cycle limit). In fact, over 40,000 Biotronik LPLDC devices are currently operating in Europe pursuant under the ETSI standard without the need of any waivers. In Canada, LPLDC is consistent with RSS-

environment outside the U.S. provides well-understood and important benefits for both manufacturers, enabling economies of scale and shorter development cycles, and patients, enabling easier international travel.

Finally, adopting LPLDC in a single channel in the existing MICS band as proposed by Biotronik would enable this center channel to be used as a “beacon” channel to alert LBT-based systems that a communication session is required, and to direct both the implant and the external device to the least interfered channel. Using a beacon to initiate an LBT session would enable implant devices to have very low current consumption. Moreover, using a beacon in the center channel is very spectrum efficient because instead of polling for an implant message the external device can transmit when requested to do so by the implant. Finally, Biotronik notes that using a single channel for LPLDC transmissions and beacon signals leaves nine additional channels plus the additional wing bands for LBT access.<sup>17</sup>

**B. LPLDC Systems That Do Not Use Frequency Monitoring Pose Little Risk of Interference to Devices That Use LBT**

As discussed above,<sup>18</sup> LPLDC systems pose little risk of interference to LBT systems because of their low power and low duty cycle. Biotronik has conducted probability analyses to show the predicted levels of interference from

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243 Issue 2 (Nov. 2005). In Australia, LPLDC access is consistent with Radiocommunications (Low Interference Potential Devices) Class License 2000 dated September 7, 2005, Schedule 1, Item 49 (without a duty cycle limit).

<sup>17</sup> See Section III.C, *infra*, for a discussion of why the center MICS channel is optimal for LPLDC transmissions.

<sup>18</sup> See Section II.A.

LPLDC systems (as proposed by Biotronik) to LBT transmissions. Even in very dense environments, the probability of interference was shown to be of the order of  $9 \times 10^{-5}$ .<sup>19</sup> In contrast, as discussed above, the inherent probability of LBT transmissions interfering with each other was found to be of the order of 0.01. Moreover, whatever negligible probability of interference that exists can be virtually eliminated using well known mitigation techniques such as forward error correction, checksums, re-transmission protocols, adaptive frequency agility, and fail-safe operating modes. Such mitigation techniques are well understood and are required due to the nature of MICS (and, later MedRadio) as a secondary user of the band.

**C. Keeping LPLDC in the 402-405 MHz Band Will Enable Less Complex and Less Expensive Dual Use Devices**

By permitting LPLDC devices to remain in the 402-405 MHz existing MICS band, the Commission would enable the production of less complex and therefore cheaper low power, dual use devices. Biotronik has relied on the existing rules to develop a targeted low power transceiver for the 402-405 MHz band, relying on the transmitter for both LBT and LPLDC access (“dual use”). Such dual use devices are advanced, low-power devices limited to the 402-405 MHz band, rather than higher-power devices capable of a wider tuning range.

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<sup>19</sup> *Ex Parte* Filing by Biotronik, Inc., ET Docket No. 06-135, RM-11271 (Sep. 25, 2006). Biotronik conducted the simulations using SEAMCAT, a publicly-available tool that has been recommended by the European Radiocommunications Office. SEAMCAT uses a statistical approach for interference analysis and has been recommended by the ERO to achieve effective spectrum usage.

Requiring dual use devices to operate using LPLDC only in the 401-402 MHz and 405-406 MHz wing bands will force such devices to use a wider transmission range, which in turn will yield a more expensive device with higher power consumption.

The complexity of an implantable medical device increases when a device capable of using a beacon must use two different sets of rules, mandating compliance with one set of requirements in the existing MICS band and a different set of bandwidth and spurious emissions limits in the newly-added wing bands. (The “complexity” of a device encompasses factors such as its parts-count, power consumption, size, and cost.) In contrast, the complexity of a device is reduced when the same device can implement beacon LPLDC and LBT sessions with similar rules in the existing MICS band. Such a reduction in complexity directly translates into fewer parts (which reduces device size and cost), lower current and power (both of which increase service life), and lower transceiver cost (which reduces the cost of the finished device as well as health care costs).

Thus, the lower device complexity that will result from devices being permitted to use a single band will lead to more reliable and less expensive devices, which in turn will make more accessible the important diagnostic and therapeutic benefits of these devices.

Finally, it is important to note that the optimal location for LPLDC access

is the center of the existing MICS band, *i.e.*, the 300 kHz channel centered at 403.65 MHz as proposed by Biotronik. An LPLDC transmission located on this central channel can simply use the device oscillator without powering up associated peripheral circuitry such as dividers, phase detectors and other circuitry in the transmitter phase-locked loop. Although the oscillator would be running “open-loop” under these conditions, it would be operating in the middle of its tuning range where its tuning characteristics are much better than at the extreme ends of its tuning range. Thus, for dual use devices, device battery drain would be minimized for the majority of transmissions (*e.g.*, periodic LPLDC transmissions). The peripheral circuitry that enables tuning can be powered up only for much less frequent follow-up LBT sessions. While such battery savings may seem inconsequential to many radio devices regulated by the Commission, they are extremely important in small, implanted medical devices. In addition, devices that only require LPLDC can be designed with fewer parts while using the same transceiver if the LPLDC transmissions were located at the center of the existing MICS band. This further reduces the complexity, size, and cost of the devices.

#### **IV. THE DEFINITION OF “BODY-WORN” DEVICES SHOULD BE CLARIFIED**

If the FCC were to allow body-worn transmitters, Biotronik seeks a clarification that a patient’s body-worn “implant programmer/control transmitter” is not classified as a body worn device subject to a 4 dB reduction in

field strength. The definition of a body-worn device should clarify that a body-worn device has a sensor or other portion implanted within the body. Any external device — *i.e.*, one that communicates via RF with an implant — requires the full legal limit of 25  $\mu$ W to communicate with that implant. As proposed, the rules appear to classify, for example, a belt-mounted device as a body worn device.

## **V. BIOTRONIK SUPPORTS FCC/FDA COLLABORATION TO ADDRESS EMI RADIATIONS THAT POTENTIALLY AFFECT IMPLANTABLE MEDICAL DEVICES**

Biotronik supports FCC efforts to enable emitter manufacturers to minimize EMI effects on medical implants. Biotronik encourages the FCC to work with the FDA and trade organizations to ensure, where possible, that new products and technologies do not radiate EMI that can affect the operation of implantable medical devices. This is particularly important for devices and technologies that may be encountered in normal day-to-day activities, such as cellular phones, retail security systems, and supply chain RFID systems.

## **CONCLUSION**

Biotronik strongly opposes the segregation of certain devices into the proposed newly added 401-402 MHz and 405-406 MHz “wing bands.” Such segregation is unnecessary given the negligible risk of interference posed by LPLDC devices. Instead, LPLDC devices should be permitted to operate in the existing MICS band on a single 300 kHz channel centered at 403.65 MHz with a

low maximum power of 100 nW EIRP and a low duty cycle.

Respectfully submitted,

BIOTRONIK, INC.

A handwritten signature in black ink that reads "Henry Goldberg". The signature is written in a cursive style with a large, stylized "H" and "G".

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